

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

**LAURA ANN HOLIZNA and KENNETH WADE HOLIZNA,**

**Plaintiffs,**

**v.**

**Civil Action No. 2:12-cv-06173**

**BOSTON SCIENTIFIC CORP.,**

**Defendant.**

**MEMORANDUM OPINION AND ORDER  
(*Defendant's Motion for Summary Judgment*)**

Pending before the court is defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment against Plaintiffs Laura Ann Holizna and Kenneth Wade Holizna [Docket 89]. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to Ms. Holizna's claims for manufacturing defect, breach of implied warranty, and breach of express warranty. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Holizna's claims for failure to warn and design defect, under theories of strict liability and negligence, and Mr. Holizna's claim for loss of consortium.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 72,000 cases currently pending, approximately 16,000 of which are in the BSC MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial

discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re: Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, available at <http://www.wvsd.uscourts.gov/MDL/boston/orders.html>). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. The Holiznas’ case was selected as a Wave 1 case by the plaintiffs.

Ms. Holizna was surgically implanted with the Obtryx Transobtrurator Mid-Urethral Sling System (the “Obtryx”) and the Pinnacle Pelvic Floor Repair Kit (the “Pinnacle”) on March 1, 2010. (BSC’s Mot. for Summ. J. & Mem. in Supp. (“Mem. in Supp.”) [Docket 89], at 2). She received the surgery at a hospital in Canton, Georgia. (*Id.*). Ms. Holizna claims that as a result of implantation of the Obtryx and the Pinnacle, she has experienced various injuries. (*See* Ms. Holizna Dep. [Docket 89-10], at 148:21–150:24). She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages. (Compl. [Docket 1], at 18–36). Mr. Holizna brings a claim for loss of consortium. (*Id.* at 32). In the instant motion, BSC moves for summary judgment on the grounds that the Holiznas’ “legal theories are without evidentiary or legal support.” (Mem. in Supp. [Docket 89], at 1).

## **II. Legal Standards**

### **A. Summary Judgment**

To obtain summary judgment, the moving party must show that there is no genuine dispute

as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict in his [or her] favor.” *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

## **B. Choice of Law**

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. “When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they

not been transferred for consolidation.” *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at \*7 (S.D. W. Va. May 25, 2010). The Holiznas’ action was originally filed in the United States District Court for the Northern District of Georgia. (Compl. [Docket 1]). Thus, the choice-of-law principles of Georgia guide this court’s choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of Georgia law. Under Georgia law, tort cases are “governed by the rule of *lex loci delicti*, which requires application of the substantive law of the place where the tort or wrong occurred.” *Carroll Fullmer Logistics Corp. v. Hines*, 710 S.E.2d 888, 890 (Ga. Ct. App. 2011) (citing *Dowis v. Mud Slingers, Inc.*, 621 S.E.2d 413, 419 (Ga. 2005)). Here, the alleged wrong occurred in Georgia, where Ms. Holizna was implanted with the allegedly defective devices. Thus, I apply Georgia’s substantive law to the claims in this case.

### **III. Analysis**

BSC argues that it is entitled to summary judgment in this case because Ms. Holizna’s claims lack either evidentiary or legal support. Ms. Holizna has agreed not to pursue claims for: (1) manufacturing defect; (2) breach of implied warranties; and (3) breach of express warranty. (Pls.’ Resp. in Opp’n to BSC’s Mot. for Summ. J. (“Resp.”) [Docket 114], at 8, 17). Accordingly,

BSC's Motion for Summary Judgment on Ms. Holizna's claims for manufacturing defect, breach of implied warranty, and breach of express warranty is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

#### A. Failure to Warn<sup>1</sup>

Under Georgia law, “[t]he manufacturer of a product which, to its actual or constructive knowledge, involves danger to users, has a duty to give warning of such danger.” *Bryant v. BGHA, Inc.*, 9 F. Supp. 3d 1374, 1383 (M.D. Ga. 2014). A manufacturer’s duty to warn may be breached in two ways: “by (1) failing to adequately communicate the warning to the ultimate user or (2) by failing to provide an adequate warning of the product’s risks.” *Id.* at 1394–95. A failure to communicate a warning may concern the “location and presentation of the warning,” while a failure to adequately warn depends upon the substance of the warning. *Id.* at 1395. Importantly, proximate cause is a necessary element for both forms of warning defect claims. *Id.*

Relevant to the analysis here, “the manufacturer of a . . . medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient’s doctor, who acts as a learned intermediary between the patient and the manufacturer.” *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003). The warnings to the doctor “must be adequate or reasonable under the circumstances of the case.” *Id.* But, “[w]here a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal

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<sup>1</sup> Ms. Holizna brings two failure to warn claims, one under a theory of negligence and the other under a theory of strict liability. Importantly, Georgia recognizes separate claims for strict liability failure to warn and negligent failure to warn. *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999). Georgia courts, however, analyze these separate claims together. See, e.g., *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 730 (Ga. Ct. App. 2003).

link is broken and the plaintiff cannot recover.” *Wheat v. Sofamor*, 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999).

Here, genuine disputes of material fact exist with regard to: (1) whether BSC’s warning to Dr. Hulse, the implanting physician, was adequate; and (2) whether the alleged inadequate warning proximately caused the alleged harm to Ms. Holizna. Therefore, BSC’s Motion for Summary Judgment on Ms. Holizna’s claims for failure to warn is **DENIED**.

### **B. Design Defect<sup>2</sup>**

Under Georgia law, to recover on a design defect claim, a plaintiff must establish: (1) that the design is defective; and (2) that the defective design caused injury. *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1364 (M.D. Ga. 2010). To establish that a design is defective, the plaintiff must prove that the risks inherent in the design outweigh the utility or benefit derived from the product. *Dean v. Toyota Indus. Equip. Mfg., Inc.*, 540 S.E.2d 233, 237 (Ga. Ct. App. 2000). The factors relevant to the risk-utility analysis include:

the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e., the user’s knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger, and the user’s ability to avoid danger; the state of the art at the time the product is manufactured; the manufacturer’s ability to eliminate the danger without impairing the product’s usefulness or making it too expensive; and the feasibility of spreading the loss in the price or by purchasing insurance.

*Id.* At the heart of this risk-utility analysis “is the reasonableness of selecting from among alternative product designs and adopting the safest feasible one.” *Jones v. NordicTrack, Inc.*, 550 S.E.2d 101, 103 (Ga. 2001). These factors, however, “are not exhaustive and do not apply in all

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<sup>2</sup> Ms. Holizna brings two design defect claims, one under a theory of negligence and the other under a theory of strict liability. The Supreme Court of Georgia has recognized that “only semantics distinguishes the cause of action for negligence and a cause of action pursuant to OCGA § 51-1-11 (claiming strict liability for defective design).” *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 674 n.3 (Ga. 1994). Accordingly, I analyze Ms. Holizna’s design defect claims together.

cases.” *Dean*, 540 S.E.2d at 237. “In general, weighing the risk-utility factors is left to the jury.” *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d at 1365. Likewise, “issues of causation are for the jury to resolve and should not be determined by a trial court as a matter of law except in plain and undisputed cases.” *Ogletree v. Navistar Int’l Transp. Corp.*, 535 S.E.2d 545, 548 (Ga. Ct. App. 2000).

Here, genuine disputes of material fact exist with regard to: (1) whether the risks inherent in the design outweigh the utility or benefit derived from the product; and (2) whether the allegedly defective design caused harm to Ms. Holizna.

Therefore, BSC’s Motion for Summary Judgment on Ms. Holizna’s claims for design defect is **DENIED**.

### C. Loss of Consortium

BSC contends that it is entitled to summary judgment on Mr. Holizna’s loss of consortium claim because loss of consortium is a derivative claim that cannot survive without Ms. Holzina’s claims. While an accurate statement of the law, because Ms. Holizna’s claims for failure to warn and design defect survive summary judgment, so does Mr. Holizna’s loss of consortium claim. BSC’s Motion for Summary Judgment on this claim is **DENIED**.

### IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC’s Motion [Docket 89] be **GRANTED IN PART** with respect to Ms. Holizna’s claims for manufacturing defect, breach of implied warranty, and breach of express warranty. BSC’s Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Holizna’s claims for failure to warn and design defect, under theories of strict liability and negligence, and Mr. Holizna’s claim for loss of consortium.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any

unrepresented party.

ENTER: May 21, 2015



A handwritten signature in blue ink, appearing to read "Joseph R. Goodwin". Below the signature, the name is printed in a black serif font: "JOSEPH R. GOODWIN" on the first line and "UNITED STATES DISTRICT JUDGE" on the second line, separated by a thin horizontal line.